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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,505	09/28/2001	Steven C. Keith	P-2776P1P1P1	5310

26253 7590 05/10/2005

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,505

Applicant(s)

KEITH, STEVEN C.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election without traverse of Group I, claims 1-15, in the reply filed on 4/20/05 is acknowledged. Please update the specification regarding the status of related cases. And please inform the examiner as to how the present specification differs from the parent application to confirm the proper priority date for this application based on the first date the claimed material was disclosed. The present abstract is incomplete, please provide a new abstract on a separate page.

This application is a CIP of 09/642,504. The single present inventor does not appear on any of the applications priority is based upon. No priority is granted because there is no common inventor, see MPEP201.11 IV, page 200-63, May 2004. Therefore priority is granted to 9/28/2001. Further searching and or consideration may be required upon resolution of this issue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon.

Bacon (Anal Chem) entitled "Determination of Oxygen Concentrations by Luminescence Quenching of a Polymer Immobilized Transition Metal Complexes" teaches in the abstract, tris(4,7-diphenyl-1, 10-phenanthroline) ruthenium(II) immobilized in a silicone rubber for measuring oxygen concentrations. On page 2780

column 2, silica gel bound luminescent dye is separated from the solution being measured. On page 2781 column 2, a number of polymers were tried and their qualities discussed. On page 2785 column 1 a silicone rubber matrix is employed to immobilize the ruthenium compound. On page 2781 column 2, calibration curves were experimentally constructed. On page 2783 the Figs. show various plots which are normalized to zero. On page 2784, H₂S acts as an interferent and totally quenches intensity acting as a control.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive.

Applicant argues that Bacon does not teach the claimed control.

It is the examiner's position that Bacon teaches a control. The present claims do not define the control other than "a control sample" which encompasses the control taught by Bacon.

Claims 1-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wodnicka.

Wodnicka (J of Biomolecular Screening) entitled "Novel Fluorescent Technology Platform for High Throughput Cytotoxicity and Proliferation Assays" teaches on page 142, column 1, fluorescence of ruthenium dyes is quenched by oxygen and is used to measure cellular respiration. The dye is immobilized in a silicone matrix.

All the presently claimed features are taught by the above references for the same function as claimed.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive.

Applicant argues that Wodnicka does not teach a control

It is the examiner's position that Wodnicka teaches a control on page 142 column 2 last full paragraph and on page 143 column 1 last paragraph. Also, see Fig. 5A on page 146, Fig. 7A on page 148, Fig. 7C on page 149, Fig. 8A and B on page 150 which teach controls.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Parker and Gentle.

Parker (Fiber Optic Sensors) entitled "Chemical Sensors Based on Oxygen Detection by Optical Methods" teaches in the abstract, fluorescence quenching to measure oxygen concentration with 9,10-diphenyl anthracene. On page 156, even when immobilized, fluorescent molecules show a reduction in fluorescence intensity with increasing oxygen concentration. Thus, solid materials can be developed to measure the concentration of oxygen. Chemical reactions that either consume or produce oxygen can be determined. The fluorescence compound may be physically immobilized in a polymer such as silicone. On page 157 the reactions take place in cuvettes.

Gentle (5,998,517) entitled "Composition for the Detection of Microorganisms in a Sample" teaches in the abstract, tris-4,7-diphenyl-1,10-phenanthroline ruthenium (II) dichloride pentahydrate to detect the growth of respiring microorganisms. In column 2 the BACTEC system uses silicone polymers as the sensor matrix because it transmits gases. See claims 11-19 in column 10.

The claims differ from each of Parker and Gentle in that they specify a control.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ a control in the method of each of Parker and Gentle because all the data obtained by the methods disclosed by the references are based upon some baseline, such as zero or 100% oxygen. To employ a control in a known assay for its known function with the expected result would have been obvious. Further, no result of the control is presently claimed. Employing computers in luminescence assays is old.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach controls and the present invention improves the sensitivity of the detection system.

It is the examiner's position that the data obtained in the references is based upon some standard. No sensitivity of the present invention is claimed.

Claims 9-11, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon.

The claims differ from Bacon in that they specify different ruthenium salts, the test sample is an enzyme, and a computer is employed in the assay.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ any known ruthenium salt known for being quenched by oxygen for the same function with the expected result as the specific ruthenium salt as specified by Bacon. No novelty is seen in the presently claimed compounds.

Regarding the selection of the sample, no novelty is seen in employing the assay of Bacon for determining any desired analyte. Employing computers in assays is old.

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive.

Applicant argues that Bacon does not teach a control.

It is the examiner's position that Bacon teaches a control. The present claims do not define the control other than "a control sample" which encompasses the control taught by Bacon.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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